LIFEPAK 1000 Defibrillators / Physio-Control, Inc. Device Notice & Correction (6/14)

Reason/Information:

Physio-Control issued an Urgent Medical Device Notice & Correction on the following materiel. Reason: Physio-Control has become aware of incidents where customers have attempted to use the LIFEPAK 1000 defibrillator and the device has shut down unexpectedly due to a very low battery. A defibrillator in this scenario has the potential to fail to deliver a shock, with the potential result that therapy is not delivered and a patient is not resuscitated.

Disposition/Instructions:

Refer to the Phyisio-Control enclosure (See Image on Message under Additional Documentation/Attachment) on how to verify the readiness of the device and determining the battery's actual charge.

Physio-Control continues to investigate this issue and will have a follow up communication with the customer regarding this issue. This communication may include updates to Operating Instructions, software updates or additional maintenance instructions.

Important Reminders

It is critically important that the customer understands what the device and battery indicators mean on the defibrillator and what actions the customer needs to take as a result. At any time the battery charge can be verified by following the instruction provided on page 2-5 of the Operating Instructions.

It is also important that the customer always carries a spare fully-charged battery, as stated in the Operating Instructions.

For general questions call Physio-Control at 800-442-1142 or 425-867-4000, Monday - Friday, 6:00 a.m. to 4:00 p.m., PDT.

Note: All LIFEPAK 1000 defibrillators are impacted by this issue. Customers with devices using batteries that are greater than 3 years of age, or who use the devices frequently are more susceptible to this issue.

Item Information:

NSN (FSC-NIIN): 6515-015783465

Nomenclature: DEFIBRILLATORS; LIFEPAK 1000

UI: EA

Manufacturer: PHYSIO-CONTROL, INC.

Service/Additional Instructions:

CONSIGNEES:WRIGHT PATTERSON AFB; PETERSON AFB; EDWARDS AFB; LACKLAND AFB; LAUGHLIN AFB; SCOTT AFB; ANDREWS AFB; KIRTLAND AFB; MCGUIRE AFB; OFFUTT AFB; FE WARREN AFB; FAIRCHILD AFB; WHITEMAN AFB; GRAND FORKS AFB; DYESS AFB; BEALE AFB; ELLSWORTH AFB; LANGLEY AFB;NELLIS AFB; DAVIS MONTHAN AFB; YOKOTA AB; ANDERSEN AB; RAF LAKENHEATH; SPANGDAHLEM AB; RAMSTEIN AB; BAGRAM AB; NHC QUANTICO; QUANTICO NHC EAST; USNH OAK HARBOR; FT BELVOIR COMMUNITY HOSPITAL (FBCH); FT CAMPBELL (BLANCHFIELD ACH); FT POLK (BAYNE-JONES ACH); FT SAM HOUSTON (BROOKE AMC); FT HOOD (DARNALL ACH); FT BLISS (WILLIAM BEAUMONT AMC); FT CARSON (EVANS ACH); FT SAM HOUSTON (USAISR); FT HUACHUCA (RAYMOND W BLISS ACH); USAMMA MAINTENANCE OPERATION; BAGRAM ARMY MLC; VILSECK (MEDDAC BAVARIA); LANDSTUHL (LANDSTUHL RMC)

ARMY:

Army activities in possession of subject equipment are required to report the status of their

work to the USAMMA NMP NLT:11-JUL-2014.

For Questions or Comments, contact: USAMMA NMP

Email: <u>usarmy.detrick.medcom-usamma.mbx.nmp-mmqc@mail.mil</u>

Phone (COMM): 301-619-6648/4464/3170

Phone (DSN): 343-6648/4464/3170

POC Contact Information:

USAMMC-E

Email: usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil

Phone (COMM): 011-49-6331-86-7118/7181

Phone (DSN): 495-7118

Fax: 6218

US ARMY

Email: <u>usarmy.detrick.medcom-usamma.mbx.doc@mail.mil</u>

Phone (COMM): 301-619-4300

Phone (DSN): 343-4300 Fax: 301-619-4468

US AIR FORCE

Email: <u>afmoa.sgalc@us.af.mil</u>
Phone (COMM): 301-619-4170

Phone (DSN): 343-4170 Fax: 301-619-2557

US NAVY

Email: <u>MMQC2@MED.NAVY.MIL</u>

Phone (COMM): 301-619-3085

Phone (DSN): 343-3085 Fax: 301-619-2473

Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In Afi 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

Additional documentation can be found by clicking here.